

Awareness Campaigns of Diseases and Health Education Regulations

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Awareness Campaigns of Diseases and Health Education Regulations

Drug section
Saudi Food & Drug Authority

For more information, please visit the website

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For inquiries

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For feedback and suggestions

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قطاع الدواء الرؤية والرسالة

Vision

To be the leading regional Drug Regulatory Authority for pharmaceuticals and cosmetic products, with professional excellence and services that contribute to the protection and advancement of public health in the Kingdom of Saudi Arabia.

الرؤية

أن يكون قطاع الدواء رائداً إقليمياً في الرقابة على الأدوية على ومستحضرات التجميل، ويقدم خدماته بمهنية متميزة تسهم في حماية وتعزيز الصحة في المملكة العربية السعودية.

Mission

Mission Protecting public health by ensuring safety, quality, efficacy and accessibility of human, veterinary drugs and biological products, and safety of cosmetics, through administration of a national regulatory system which is consistent with international best practice. Through our mission, we also provide accurate and scientific-based information to the public and healthcare professionals.

الرسالة

حماية الصحة العامة من خلال ضمان أمان وجوده وفعالية وتوفير الأدوية البشرية والبيطرية والمنتجات الحيوية وسلامة مواد التجميل عبر تطبيق نظام وطني للرقابة متوافق مع أفضل الممارسات الدولية وتقديم المعلومات الدوائية المبنية على أسس علمية للعامة والمهنيين الصحيين.

Certified document:

Copy	Date	publisher	Notes
1	2011/11	Management Executive for Licenses	-
2	2015/4	Management Executive for Licenses	update

Introduction:

Due to the society need of awareness and health education about some diseases -from time to time- regarding how to treat and prevent them. Proceeding from the rule of Saudi Food & Drug Authority in supporting and activating the educational health awareness program. In order to provide correct and balance awareness information, SFDA have considered making these regulations.

The regulations aim:

These regulations aim to organize the awareness campaigns about diseases, some health conditions and the health education which are funded by pharmaceutical establishments (contained in the first Act in pharmaceutical products and establishments Law), directed towards the public by the specialized department of Saudi Food & Drug Authority.

The general principles of awareness campaigns:

- 1- **Accuracy:** Information has to be correct and accurate, thus the public opinion will not be misguided by incorrect information. And it shall view the health and educational

information about how to deal with disease and health conditions.

- 2- **Currency of the information:** The information shall be up to date and it shall be noted clearly about that information publishing date.

- 3- **Documentation:** The information is scientifically authenticated by returning to medical references or other valued scientific sources.

- 4- **Source definition:** The scientific sources and resources shall be defined and clear in the sheet. In case of quotation, the quoted text shall be clear and distinct from the general text content. In addition, the quotation source shall be mentioned.

- 5- **Comprehensiveness:** The main properties of the awareness sheet subject shall be covered. Thereby contributing to rising the audience's health education level.

- 6- **Balance:** Clarifying the implications of transmitting and spreading the disease realistically and without

exaggeration. In addition, offering different treatment options in a balanced manner.

- 7- **Legibility:** The used language shall be clear, correct, and easy to read for the public. It shall be supported by graphic design and suitable format.
- 8- **Advertising:** The campaign shall be free from all drug brand names, the shape of the pack or any other product that has denotations or symbols.

Awareness Campaigns Conditions:

- 1- The campaign shall not conflict to Islamic Law tenets.
- 2- The campaign shall not contain any violations of public decency or customs and traditions of society.
- 3- Identifying the target groups of society in the campaigns.
- 4- The campaign shall contain messages regards public health: (means of protection, diagnosis and all the treatment options).
- 5- Pharmaceutical products brand names shall not be mentioned.

- 6- Lack of reference explicitly or implicitly to a treatment option in which it has an advantage over another treatment option.
- 7- The campaign shall not be encouraging diagnosis and self-treatment.
- 8- Avoiding exaggeration or intimidation that may cause fear and panic among all members of society.
- 9- Emphasizing on the necessity of reviewing and consulting specialized health practitioner.
- 10- Obligating to what have been mentioned in the Saudi Code of Pharmaceutical Promotional Practices.

Regulations and provisions of awareness campaigns websites:

- 1- the name of scope shall be clear and expressive on the content directly.

- 2- The scope shall be registered in the Kingdom of Saudi Arabia.

- 3- The scientific material shall be available in the same website. In addition, the website shall not be depended on providing the main information on external links.
- 4- The user shall be linked by the website with links or other websites that have extra information after gaining SFDA approval.
- 5- The pages last update time shall be added clearly.
- 6- The SFDA approval shall be obtained before doing any adjustment, update or change to the website.
- 7- SFDA has the right to stop a part or the whole website in case of updates.
- 8- The website shall be promoted in a balanced and reasonable way.
- 9- The Arabic language used in the website shall be clear and free from spelling and grammatical errors.
- 10- Providing information directed at health care professionals (HCPs) in the website is not allowed in any way.
- 11- A link shall be added to the SFDA models to report on the side effects among the website.

12- Adding the contact details of the National Drug & Poison Information Center (NDPIC) that is related to SFDA among the website.

The minimum information that shall be in the awareness campaign:

- 1- Mentioning the causes of the disease or the kind of condition and its hazards in a simple way.
- 2- Providing preventive and diagnostic information and the suitable treatment options in an accessible form.
- 3- Providing advices directed to patients, such as, (in case of having any side effect of drugs, the patient shall report on them by calling the National Pharmacovigilance and Drug Safety Center).
- 4- The available mechanism for further information: valued sources shall be mentioned for reference. Such as, (National Drug & Poison Information Center).

The validity period of the campaign license:

Two Hejri years unless the applicant requested less amount of time than that, or if new updates need to be reviewed in the information provided in the campaign.

General provision:

- 1- SFDA has the right to cancel the health educational and awareness of disease campaign license whenever it is approved that the licensee establishment has violated this regulation.
- 2- SFDA has the right to stop the campaign temporarily for any reason.
- 3- SFDA has the right to transfer the violated establishment to The Committees of Violations to impose the appropriate penalty.
- 4- SFDA has the right to maintain supervision and oversight on the general content of the campaign during the period of validity of the license.

Consent method:

1- Filling out the consent form for the Awareness campaign of disease and health education. (Attachment 1).

2- Filling out and stamping the form of the obligation (Attachment 2).

3- Paying services charges.

4- Attaching the proposed campaign content on adjustable digital CD.

Annexes:

1- The application form of consent form on Awareness Campaign of Disease and Health Education.

2- The form of obligation.

Form No. (1) Awareness Campaign of Disease and Health Education application form

Awareness campaign of disease and health education data	
Campaign title:	
Campaign topic:	
Language of the campaign:	<input type="radio"/> Arabic <input type="radio"/> English
establishment name that is funding the campaign:	
Agent:	
Implementers (in case it differs from funded company or the agent):	
Awareness campaign	
Awareness campaign nature (you cannot choose more than three choices)	<input type="radio"/> Readable <input type="radio"/> Audible <input type="radio"/> Visible <input type="radio"/> Phone messages <input type="radio"/> Email <input type="radio"/> Billboard <input type="radio"/> Other:.....
Target group:	
The duration of the campaign:	
The classification of the application	
The classification of the application:	<input type="radio"/> New application <input type="radio"/> Renew application <input type="radio"/> Reword the campaign <input type="radio"/> Other:.....
In case the choice is renew the campaign, how many are the previous campaign:..... .Number of application for approval on the campaign of awareness.....	
Applicant information	
Authorized person name:	
Working place:	
Job:	<input type="radio"/> Scientific office manager <input type="radio"/> Regulatory affairs manager
Phone number:	
Email:	

I declare that all information included in this application and indexes is correct and active, and there are no restrictions or pending cases in courts or any other official bodies against each and every and with regards to advertisement as parties, institutions and products.

The Official Stamp

Requested party:

Name of the responsible person

Signature

Index No. (2): obligation

Saudi food & drug Authority

May peace and blessings be upon you,

**Regarding to the attached application containing the request for approval of
Disease awareness and health education campaigns:**

Name of campaign:

The company or financing entity:

Therefore, we declare the following:

- No using the campaign after the ending of the specified period which is two Hijri years from the date of final approval.
- No adding or deleting any information after taking the final approval.
- Adding the number of the SFDA approval resolution on the campaign.
- Compliance with the Law of establishments and pharmaceutical products and the Law of Saudi Food & Drug Authority and its implementing regulation.
- Providing SFDA with a copy of the campaign before publication.
- No claiming to refund after submitting the application.

The Official Stamp

Requested party:

Name of the responsible person

Signature